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SENSITIVE
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DEPARTMENT FOR OES/IHA
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SUBJECT: RUSSIA RISES AS MAJOR CENTER FOR CLINICAL DRUG TRIALS

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¶1. (SBU) SUMMARY: With the volume of clinical drug trials in Russia enjoying rapid growth over the past few years, Russia has become the market leader for clinical drug trials among the BRIC countries (Brazil, Russia, India and China). Russia enjoys numerous advantages in conducting trials, including a centralized health care system, availability of skilled doctors, and large cohorts of treatment-naive patients. END SUMMARY.

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Russian Clinical Trials Market Takes Off
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¶2. (SBU) The number of clinical trials approved in Russia grew by 11 percent in 2007 compared to 2006, and by 16 percent in 2006 compared to 2005, according to data compiled by the Federal Service for Health and Social Development (Roszdravnadzor). Russia has emerged as the clear leader among the BRIC countries with a total of 713 FDA clinical drug trials currently on-going (Brazil is in second place with 390 FDA clinical drug trials), according to CenterWatch, a clinical drug trial listing and information service. Some 50 percent of drug trials in Russia are in late-stage, Phase III testing. Foreign firms sponsored over 65 percent of all drug trials approved in Russia in 2007. Leading multinational pharmaceutical companies such as Sanofi-Aventis, Merck, GlaxoSmithKline, Boehringer Ingelheim and Novartis have become leaders in Russia's clinical drug trials market. The most popular areas of clinical drug trial research are treatments for cardiovascular disease, cancer, psychiatry (including medicines for depression and schizophrenia), and neurology (medicines for multiple sclerosis and Parkinson's disease).

¶3. (SBU) While most drug companies still conduct trials in Russia through their own research departments, a growing number of companies are outsourcing trials to contract research organizations (CROs), independent multinational firms that specialize in conducting ethical and unbiased drug trials. CROs are now conducting 42% of all Russian drug trials, up from 30% three years ago. Over ten major and fifty smaller CROs now operate within Russia.

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Russia's Advantages in Clinical Drug Research
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¶4. (SBU) The centralized medical system in Russia is perfect for

clinical drug trials, because large numbers of patients with similar illnesses are found at the same treatment centers, according to our CRO and pharmaceuticals contacts. The relatively high quality of Russian doctors also means that the quality of the trials is often as good as trials conducted in Western Europe. Although many Russian doctors do not speak English, there are six times more doctors in Russia per capita than in India. The high amount of treatment-naive patients in Russia (i.e., patients who have never before received medicine or treatment for a particular ailment) offers a large pool of potential test subjects that is not available in many other countries.

¶5. (SBU) One CRO representative told us that the main disadvantage of clinical drug trials in Russia is the high customs duties for imports of drugs used in trials. Other experts cite the 1.5-month-long paralysis of the economy during the summer 'dacha' season and strict regulations for drug trials from Roszdravnadzor as additional concerns. Even so, the waiting period for trial approvals from Roszdravnadzor is only three months in Russia, as opposed to eight to twelve months in China. Many industry players consider that the high customs duty is offset by the comparatively low costs of conducting drug trials in Russia. The cost savings in Russia stem primarily from the relative ease in recruiting and enrolling large volumes of patients.

¶6. (SBU) While noting that the market was growing at a rate of at least 15% per year, one pharmaceutical industry contact complained that the market was beginning to become saturated. The boom in drug trials began three years ago, and all of the main clinical and hospital centers in Moscow and St. Petersburg are now running multiple trials and do not have the capacity or staffing to handle more. This has forced some major companies to move drug trials to other cities such as Novosibirsk and Nizhny Novgorod, which have more drug-naive patients and hospitals with more capacity and



staffing to begin new trials.

¶7. (SBU) According to one CRO industry representative, the June 2007 temporary ban on exports of all human biological samples (Reftel) had a significant impact on the clinical drug trial market, interrupting trials for several weeks and ruining many samples in need of export to Europe and the United States for further analysis. However, another drug company representative felt that the brevity of the ban, lasting only a few weeks, inflicted no major long-term damage to the clinical drug trials market aside from creating worry in the industry that the ban might be repeated at some point in the future. While there are no signs that the export ban would reoccur, a growing number of CROs and pharmaceutical companies are considering establishing their own proprietary testing labs in Russia, or partnering with an existing Russian lab, to handle all testing for trials within Russia. To help meet the demand for testing of biological samples from drug trials and to ensure the availability of independent testing expertise within Russia, Roszdravnadzor is also establishing a government-owned central testing lab that will be accredited by the European laboratory accreditation body, and has plans to set up seven other regional testing labs.

¶8. (SBU) One pharmaceutical representative told us that Russia could, in theory, also become a major center for the testing of pediatric medicines, but that the lack of legislation regulating pediatric drug trials was a significant impediment to developing that segment of the market. There is a growing worldwide demand for research and development of pediatric drugs, and within Russia itself, demand for childhood medicines is high, but few drugs are registered for children. In 2005, a poorly conducted trial on a childhood vaccine was halted and spawned lawsuits by the parents of some children allegedly harmed by the trial. Those lawsuits are still making their way through the Russian court system. A leading Russian patients' rights advocate has also claimed that Russian doctors and PhD candidates sometimes engage in unethical and illegal clinical trials in order to gather research data. The Federation Council (Russia's upper parliamentary house) is currently drafting legislation to regulate pediatric drug trials in consultation with industry and government representatives.

¶9. (SBU) COMMENT: We believe the clinical drug trials market will continue to expand over the next few years in light of Russia's numerous advantages in hosting drug trials, including the relatively low cost of trials, centralized health care system, large cohorts of treatment-naive patients, and the availability of skilled doctors. This trend is likely to continue despite some minor impediments such as the temporary export ban, high customs duties for drug imports used in trials, and the relative saturation of drug trial sites in Moscow and St. Petersburg. As the market continues to develop, CROs and pharmaceutical companies will increasingly look outside of Russia's two largest cities for sites to host trials.

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